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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,878	11/14/2001	Albert Sattin	30429-CIP	6972

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	8

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,878	SATTIN ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) 5-32 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to tripeptides, classified in class 514, subclass 18.

II. Claims 5-10, drawn to method of treating depression, schizophrenia or affective disorder, classified in class 514, subclass 18.

III. Claims 11-18, drawn to method for providing therapy for drug dependence using tripeptides, classified in class 514, subclass 18.

IV. Claims 19-26, drawn to method for providing analgesia using tripeptides, classified in class 514, subclass 18.

V. Claims 27-32, drawn to method of inducing analeptic stimulation, classified in class 514, subclass 18.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the tripeptides of the claimed invention can be used for a materially different purpose such as decreasing the duration of sleep caused by barbiturates. This is a materially different process from all of the claimed methods of Group II-V because this method does not require the same subjects and has a different end result as the method of Group II-V.

The method of Group II-V are different patentably distinct from one another because they are different methods. The method of Group II, which is the treatment of depression and

schizophrenia would have different subjects from a method of providing analgesia. Further, the end point, where the culmination of the method is achieved would be entirely different from one another. Thus the methods are patentably distinct.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V, or vice versa, restriction for examination purposes as indicated is proper.

During a telephone conversation with Stephen Slusher on 9-29-03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claim 5-32 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim1 is rejected under 35 U.S.C. 102(b) as being anticipated by Szirtes et al. (GB2109796).

The claims are drawn to pharmaceutical preparation of tri peptides pGlu-R1-Pro, wherein R1 is Leu, Tyr, Val and wherein pGlu is defined to be pyroglutamine. The claims do not recite what functionality terminates the C-terminus of the tri peptide.

The reference discloses tripeptides have anorexigenic activity of the formula X-Y-Pro-OH (see abstract). The reference specifically discloses peptides Glp-Leu-Pro-OH, Glp-Val-Pro-OH, and Glp-Tyr-Pro-OH (see page 4, table 2). The reference states that the peptides are used in therapy as pharmaceutical compositions and can comprise pharmaceutically acceptable inorganic or organic carriers (see page 2, lines 6-10).

Note that Glp is defined as pyroglutamyl. This is specifically defined by the examples which cite the entire name of the tripeptide and then abbreviated in the actual example. For example, the first example discloses a method of preparing "L-pyroglutamyl-L-leucyl-L-proline (see page 2). The end product obtained is disclosed to be "Glp-Leu-Pro-OH." (see page 3, lines 30-32) Thus, there is sufficient teaching to indicate the Glp=pyroglutamine.

The reference therefore anticipates the claims.

2. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sievertsson et al. (J. Medicinal Chemistry).

The claims are drawn to pharmaceutical preparation of tri peptides pGlu-R1-Pro, wherein R1 is Leu, Tyr, Val and wherein pGlu is defined to be pyroglutamine.

The reference teaches the administration of the synthesized peptide pGlu-Tyr-Pro-NH2 at a dosage of up to 50μg to determine hormonal activity in mice (see page 220, second column). The peptides are injected with .009μg into the mice to determine the hormonal activity (see page 221 table IV). The standard used against the peptide was saline (see table IV). Therefore, the

pharmaceutical carrier taught by the reference is saline. Since the reference discloses the administration of the tripeptide via injection into mice, the reference anticipates a pharmaceutical preparation of tripeptide.

3. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kisfaludy et al. (US4299821).

The claims are drawn to pharmaceutical preparation of tri peptides pGlu-R1-Pro, wherein R1 is Leu, Tyr, Val and wherein pGlu is defined to be pyroglutamine.

The reference teaches the administration of the synthesized peptide of the formula Glp-X-Y-NH-A (see abstract and claim 1). The reference anticipates the claimed invention when X is allowed to be L-valyl (valine), Y is L-prolyl (proline) and A is hydrogen (see abstract and claim 1). Note that Glp is defined to be pyroglutamyl (see col. 1, lines 30-32). The reference teaches that the peptides can be manufactured into pharmaceutically acceptable salts or complexes for the treatment of decreasing the duration of sleep caused by barbiturates, for example (see claim 5 and column 5, lines 30-43).

Even though the peptide is chosen from a markush, the MPEP states that "If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." See MPEP 2131.02. Here, not only can one of ordinary skill in the art draw the structure of the compound but one can also name the each of the compounds from the generic formula. Thus the claimed compound pGlu-Val-Pro-NH2 is "at once envisage" and is anticipated by the reference.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kisfaludy et al. (US4386073).

The claims are drawn to pharmaceutical preparation of tri peptides pGlu-R1-Pro, wherein R1 is Leu, Tyr, Val and wherein pGlu is defined to be pyroglutamine.

The reference teaches the administration of the synthesized peptide of the formula X-Y-W-NH2 (see abstract and claim 1). The reference anticipates the claimed invention when X is allowed to be L-pyroglutamyl, Y is L-Leucyl, and W is L-prolyl (proline) (see abstract and claim 1) The reference teaches that the peptides can be manufactured into pharmaceutically acceptable salts or complexes for the treatment of decreasing the duration of sleep caused by barbiturates, for example (see claim 11 and column 5, lines 34-45).

Even though the peptide is chosen from a markush, the MPEP states that "If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." See MPEP 2131.02. Here, not only can one of ordinary skill in the art draw the structure of the compound but one can also name the each of the compounds from the generic formula. Thus the claimed compound pGlu-Leu-Pro-NH2 is "at once envisage" and is anticipated by the reference.

5. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Szirtes et al. (J. Med. Chem.)

The claims are drawn to pharmaceutical preparation of tri peptides pGlu-R1-Pro, wherein R1 is Leu, Tyr, Val and wherein pGlu is defined to be pyroglutamine.

The reference teaches peptide of the formula pGlu-Leu-Pro-NH2 and pGlu-Val-Pro-NH2, listed as peptides 3 and 6 in table III respectively (see page 743). The reference discloses that the peptides were synthesized, isolated and formulated into pharmaceutical composition do determine the hormonal activity and anticataleptic effect in Wistar rats (see table III and page 744, Experimental section). The reference discloses the pharmaceutical formulation were for intravenous administration (see page 744, Experimental section). The reference discloses that analogs 3 and 6, had powerful anticataleptic effect (see page 744, first column). Thus the reference anticipates the claimed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

9/19/07

Anish Gupta
Patent Examiner